

ANESTHESIOLOGISTS for the SAFE ADMINISTRATION of PROPOFOL

August 17, 2005

Dear Colleague,

I am writing to you in regard to a potentially dangerous patient safety issue. On June 28th, a petition was filed with the US Food and Drug Administration that has the potential to cripple our specialty through the erosion of our professional sovereignty and the patient advocacy and safety for which it stands. The petition was filed by the American College of Gastroenterology (ACG) and is related to the administration of Propofol (Diprivan) during endoscopic procedures.

Currently, the warning label on this potent anesthetic specifically states:

For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available.

The petition is asking that the FDA remove the specifications requiring individuals to be trained in the administration of general anesthesia. As anesthesiologists, we have significant training and years of experience in advanced airway support and resuscitative skills—all necessary when administering Propofol. As you know there are no reversal agents for this anesthetic, and loosening the restrictions could only lead our advocacy for patient safety down a perilous slippery slope.

The ACG is on record as saying this initiative is related to the reimbursement costs for anesthesiologists. It is our professional and personal opinion that putting economic interests before patient care seems counter to our mission. Our job is to create the safest and most effective surgical environment for surgeons and patients. It also means educating these societies to ensure that patients are not simply receiving the right medication, but also that it is being administered by the most adroit professional.

I would like you to consider reading and signing the attached "call to action" letter addressed to the Food and Drug Administration. As anesthesia professionals, we have a responsibility to ourselves, to our profession and, most importantly, to our patients. We must not ignore this grave issue. As stewards of patient safety, we must assiduously work to advocate against interests that serve to undermine years of hard work and advancements in medicine.

For more information on the status of this petition and our advocacy efforts, please visit www.safepropofol.org.

Respectfully Yours,

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